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degrees C.

C8 27. (Amended) The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 70 degrees C.

Please add the following new claims:

19-69. The method of claim 1, further comprising:  
detecting a temperature of the skin surface.

C9 20. The method of claim 19, wherein delivering energy to the collagen containing tissue site includes delivering a sufficient amount of energy to the tissue site in response to the detected temperature of the skin surface to tighten the loose skin surface.

## REMARKS

This Preliminary Amendment is in response to the Examiner's Final Office Action mailed June 13, 2000. Claims 3-7, 13-16 and 28-68 are canceled. Claims 1-2, 8-12, and 17-27 are amended. New claims 69-70 are added. Claims 1-2, 8-12, 17-27, and 69-70 are now pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order which the corresponding issues were raised in the Office Action.

### I. Rejections under 35 U.S.C. §112

Claims 1- 68 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has canceled claims 3-7, 13-16 and 28-68. In response to the Examiner's rejection on the grounds that "in order to further limit a method, an apparatus must manipulatively affect the method" and "functional description must be sufficiently precise", Applicant amends claims 1-2, 8-12, and 17-27

to positively recite manipulative steps of the claimed method. Applicant submits that these amendments should address the issues raised by the Examiner under 35 U.S.C. §112, second paragraph. Withdrawal of this ground of rejection is respectfully requested.

**II. Rejections under 35 U.S.C. §102(e)**

Claims 28-40 are rejected under 35 U.S.C. §102(e) as being anticipated by Eggers et al. (U.S. Patent No. 5,697,909). Applicant has cancelled claims 28-40. The Examiner's rejection is rendered moot by this amendment.

**III. Rejections under 35 U.S.C. §103(a)**

Claims 1-27 and 41-68 stand rejected as being obvious over Neeffe in combination with Sand ('709). In response to the Examiner's rejection under §103(a), Applicant cancels claims 3-7, 13-16 and 41-68 and amends claims 1-2, 8-12, and 17-27.

The Examiner states that

Neeffe teaches a collagen shrinkage method using various type of energy. Sand ('709) teach a method of shrinkage collagen using light. It would have been obvious to the artisan of ordinary skill to employ various forms of heating energy in the method of Sand ('709) since these are equivalents as taught by Neeffe, thus producing a method such as claimed.

The Examiner Office Action, Paper 11, page 4, lines 9-13.

Applicant amends independent claim 1 to specify that in the claimed method the energy is delivered to the loose skin surface by producing the energy from an energy source and by contacting an energy delivery surface of the energy source with the skin surface. Support for the claim language appears in the Specification, page 10, lines 4-5.

Neeffe does not teach or suggest the claimed method as amended. Neeffe teaches a method of correcting refractive errors of the eye by reshaping the cornea using a concave mold and applying heat or other forms of energy to the mold. Column 1, lines 34-49. Specifically, Neeffe teaches heating the mold first, applying the mold to the eye, and maintaining the temperature of the mold by irradiating the mold while the mold is held in place of the cornea. Column 1, lines 44-49. Thus, the energy delivered to the cornea is produced by an energy source external to the mold and transferred to the cornea surface via thermal equilibrium between the mold and cornea. Therefore, Neeffe fails to teach the step of delivering energy to a collagen containing tissue site by producing the energy from an energy source and contacting the energy delivery surface of the energy source with the skin surface.

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The secondary reference, Sand ('709), does not provide these claimed steps missing in Neeffe. Sand teaches a method of reshaping cornea by directly irradiating the cornea using laser. See Summary of the Invention in Sand. There is neither teaching nor suggestion of the claimed step of producing the energy from an energy source and contacting the energy delivery surface of the energy source with the skin surface. Instead, Sand teaches irradiating the cornea a coherent light source, laser, without contacting the cornea surface. Specifically, "the optical-delivery-system laser is integrated with the corneal mapping or topography system to enable computer control of laser output, as well as real-time monitoring of progressive corneal reconfiguration". Column 6, lines 37-41. Thus, the combination of Neeffe and Sand fails to teach all of the steps in the claimed method. Therefore, the claimed invention is not rendered *prima facie* obvious by the combination of Neeffe and Sand.

Further, combination of the Neeffe's method with Sand's would render Neeffe's method inoperable. Neeffe teaches reshaping cornea using a corrective mold "made of metal such as stainless steel, platinum, gold alloys or other inert metal". Column 1, lines 41-43. By contrast, Sand teaches using laser to directly irradiate cornea. To minimize trauma of the corneal tissue layers anterior and posterior of the stroma, Sand stresses the criticality of the timing of energy delivery and the importance of accurate determination of the collagen absorption coefficients in the cornea. Column 4, lines 32-44. Thus, applying a mold to the cornea as taught by Neeffe would erect a physical barrier between the cornea and the laser beam and completely change the energy absorption profile desired by Sand. Facing such a problem, one of ordinary skill in the art would not be motivated to modifying Neeffe in view of Sand to arrive the present invention.

In view of the above-described features of the claimed invention that distinguish from the cited references, Applicant submits that the claimed method is not rendered obvious by Neeffe and Sand, either alone or in combination. Withdrawal of this ground of rejection is respectfully requested.

### CONCLUSION

In light of the Amendments and the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

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The Commissioner is authorized to charge any fees which may be required, including petition fees and extension of time fees for a small entity, to Deposit Account No. 23-2415 (Docket No. 16904-727).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

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